

3. Plaintiff PF Consumer Healthcare 1 is a limited liability company organized and existing under the laws of Delaware and having a place of business at 1209 Orange Street, Corporation Trust Center, Wilmington, DE, 19801.

4. Defendant ZeaVision LLC (“ZeaVision”) is a limited liability company organized and existing under the laws of Delaware with an address of 716-I Crown Industrial Court, Chesterfield, MO 63005. On information and belief, ZeaVision is doing business within this district.

JURISDICTION AND VENUE

5. This Court has jurisdiction under 28 U.S.C. §§ 1331 and 1338(a) and (b).

6. This Court has personal jurisdiction over ZeaVision. On information and belief, ZeaVision, directly or through its alter ego, affiliates, or agents, develops, formulates, manufactures, markets, and sells vitamin products throughout the United States, including in New York and this judicial district. On information and belief, ZeaVision regularly conducts and solicits business in the State of New York, engages in other persistent courses of conduct in the State of New York, and/or derives substantial revenue from services or things used or consumed in the State of New York. On information and belief, ZeaVision transacts business within the State of New York related to Bausch & Lomb’s claims, and has engaged in systematic, pervasive, and continuous business contacts within the State of New York and this judicial district.

7. Personal jurisdiction is also proper over ZeaVision in this judicial district because ZeaVision operates an interactive website accessible to New York consumers in which it has advertised the EyePromise® AREDS 2 Plus Multi-Vitamin, EyePromise® AREDS 2 Plus Zinc Free, and EyePromise® Zeaxanthin + Lutein products. ZeaVision is offering the products for sale to consumers within this judicial district via the website located at www.eyepromise.com.

8. On information and belief, venue is proper in this Court pursuant to 28 U.S.C. §§ 1391 and 1400(b).

CLAIMS FOR RELIEF

COUNT 1: PATENT INFRINGEMENT OF U.S. PATENT NO. 6,660,297

9. Bausch & Lomb is a joint owner and licensee of all rights in the field of ophthalmology, including the right to enforce, of United States Patent No. 6,660,297 (“the ’297 Patent”) which was duly and lawfully granted on December 9, 2003 to Stephen P. Bartels, Cara L. Baustian, George E. Bunce, Leon Ellenbogen, Frederick L. Ferris III, Jin Kinoshita, James C. Smith and David A. Souerwine for an invention in “Nutritional Supplement to Treat Macular Degeneration.” PF Consumer Healthcare 1 is a joint owner of the ’297 Patent. Pursuant to 35 U.S.C. § 207(a) and the exclusive license received from the U.S. government joint owner, including the right to enforce the ’297 Patent, Bausch & Lomb can maintain this action without the U.S. government as a party. A true copy of the ’297 Patent is attached as Exhibit A.

10. The ’297 Patent describes and claims, among other things, methods and compositions useful as nutritional supplements for prevention, stabilization and/or treatment of visual acuity loss by reducing the risk of age-related macular degeneration and cataracts and for maintaining and preserving eye health and vision. The invention of the ’297 Patent provides, *inter alia*, a formulation dosage of vitamin A in the form of beta-carotene (substituted or supplemented with lutein, zeaxanthine or a combination thereof), vitamin C, and vitamin E, as well as zinc and copper.

11. On or about September 10, 2007, a request for an *inter partes* reexamination of the ’297 Patent was filed in the United States Patent and Trademark Office (“PTO”). On or about April 30, 2013, the PTO issued an *Inter Partes* Reexamination Certificate wherein the PTO

determined: (1) claims 1-4, 10, 18 and 19 of the '297 Patent were patentable as amended; (2) claims 5, 6, 8, 9, 11, 12 and 14-17 of the '297 Patent were patentable; and (3) new claims 22 through 32 were patentable. A true copy of the *Inter Partes* Reexamination Certificate for the '297 Patent is attached as Exhibit B.

12. Bausch & Lomb markets and sells products covered by the '297 Patent within this district and elsewhere in the United States, including but not limited to its PreserVision® AREDS and AREDS 2 Formula products, with notice to the public that such products are patented by affixing to the package of those products a label identifying the '297 Patent.

13. ZeaVision is infringing, inducing infringement of, and/or contributing to the infringement of the '297 Patent by making, using, offering to sell, selling, or importing, within this district or elsewhere in the United States, compositions or methods covered by the '297 Patent and/or by selling, offering for sale and/or importing compositions with instructions for use or promotions that cause and induce the user to infringe the claims in the '297 Patent, and/or by selling, offering to sell or importing components or materials, knowing the same to be especially made or especially adapted for use in an infringement of the '297 Patent.

14. ZeaVision is making, using, importing, offering to sell, or selling compositions containing a formulation of lutein, zeaxanthin, vitamins C and E, zinc, and copper that are specifically described and claimed in the '297 Patent, including but not limited to ZeaVision's EyePromise® AREDS 2 Plus Multi-Vitamin product. ZeaVision is making, using, importing, offering to sell, or selling such compositions for the use in treating or preventing age-related eye disease or for maintaining or preserving eye health or vision, which infringe the claims of the '297 Patent.

15. On information and belief, ZeaVision is selling, offering for sale and/or importing compositions with instructions for use and promotions that cause and induce the user to infringe the claims in the '297 Patent, including but not limited to ZeaVision's EyePromise® AREDS 2 Plus Multi-Vitamin product.

16. On information and belief, ZeaVision is selling, offering for sale and/or importing components or materials, knowing the same to be especially made or especially adapted for use in an infringement of the '297 Patent.

17. On information and belief, ZeaVision became aware of the '297 Patent on or after its issuance date of December 9, 2003. On information and belief, ZeaVision has willfully infringed the patent by continuing to make, use, offer for sale, sell, or import ZeaVision's EyePromise® AREDS 2 Plus Multi-Vitamin product.

18. ZeaVision is on notice that Bausch & Lomb's own products, including but not limited to PreserVision® AREDS and AREDS 2 Formula products, are proprietary.

19. The aforesaid sales and acts by ZeaVision are without right, license or permission from Bausch & Lomb.

20. On information and belief, ZeaVision intends to continue the sales and acts referred to in paragraphs 13-19.

21. Bausch & Lomb has been damaged by ZeaVision's infringement of the '297 Patent and will be irreparably damaged if that infringement is not enjoined.

COUNT 2: PATENT INFRINGEMENT OF U.S. PATENT NO. 8,603,522

22. Bausch & Lomb incorporates herein and realleges as if fully set forth in this Paragraph, the allegations of Paragraphs 1 through 8 above.

23. Bausch & Lomb is a joint owner and licensee of all rights in the field of ophthalmology, including the right to enforce, of United States Patent No. 8,603,522 (“the ’522 Patent”) which was duly and lawfully granted on December 10, 2013 to Stephen P. Bartels, Cara L. Baustian, George E. Bunce, Leon Ellenbogen, Frederick L. Ferris III, Jin Kinoshita, James C. Smith and David A. Souerwine for an invention in “Nutritional Supplement to Treat Macular Degeneration.” PF Consumer Healthcare 1 is a joint owner of the ’522 Patent. Pursuant to 35 U.S.C. § 207(a) and the exclusive license received from the U.S. government joint owner, including the right to enforce the ’522 Patent, Bausch & Lomb can maintain this action without the U.S. government as a party. A true copy of the ’522 Patent is attached as Exhibit C.

24. The ’522 Patent describes and claims, among other things, methods for stabilization and/or treatment of visual acuity loss by reducing the risk of age-related macular degeneration and cataracts and for maintaining and preserving eye health and vision. The invention of the ’522 Patent provides, *inter alia*, a method of administering a formulation of lutein-zeaxanthine combination or vitamin A in the form of beta-carotene (substituted or supplemented with lutein, zeaxanthine or a combination thereof), vitamin C, and vitamin E, as well as zinc and copper.

25. Bausch & Lomb markets and sells products for the methods covered by the ’522 Patent within this district and elsewhere in the United States, including but not limited to its PreserVision® AREDS and AREDS 2 Formula products.

26. ZeaVision is infringing, inducing infringement of, and/or contributing to the infringement of the ’522 Patent by making, using, offering to sell, selling, or importing, within this district or elsewhere in the United States, products for the methods covered by the ’522 Patent and/or by selling, offering for sale and/or importing compositions with instructions for use or

promotions that cause and induce the user to infringe the claims in the '522 Patent, and/or by selling, offering to sell or importing components or materials, knowing the same to be especially made or especially adapted for use in an infringement of the '522 Patent.

27. ZeaVision is making, using, importing, offering to sell, or selling compositions containing a formulation of lutein, zeaxanthin, vitamins C and E, zinc, and copper, that are specifically described and claimed in the '522 Patent, including but not limited to ZeaVision's EyePromise® AREDS 2 Plus Multi-Vitamin product. ZeaVision is making, using, importing, offering to sell, or selling such compositions for the use in treating or preventing age-related eye disease or for maintaining or preserving eye health or vision, which infringe the claims of the '522 Patent.

28. On information and belief, ZeaVision is selling, offering for sale and/or importing compositions with instructions for use and promotions that cause and induce the user to infringe the claims in the '522 Patent, including but not limited to the EyePromise® AREDS 2 Plus Multi-Vitamin product.

29. On information and belief, ZeaVision is selling, offering for sale and/or importing components or materials, knowing the same to be especially made or especially adapted for use in an infringement of the '522 Patent.

30. On information and belief, ZeaVision became aware of the '522 Patent on or after its issuance date of December 10, 2013. On information and belief, ZeaVision has willfully infringed the patent by continuing to make, use, offer for sale, sell, or import ZeaVision's EyePromise® AREDS 2 Plus Multi-Vitamin product.

31. The aforesaid sales and acts by ZeaVision are without right, license or permission from Bausch & Lomb.

32. On information and belief, ZeaVision intends to continue the sales and acts referred to in paragraphs 26-31.

33. Bausch & Lomb has been damaged by ZeaVision's infringement of the '522 Patent and will be irreparably damaged if that infringement is not enjoined.

COUNT 3: FALSE ADVERTISING

34. Bausch & Lomb incorporates herein and realleges, as if fully set forth in the Paragraph, the allegations of Paragraphs 1 through 8 above.

35. Bausch & Lomb and ZeaVision are competitors in the eye health vitamin market.

36. Bausch & Lomb distributes eye health vitamins under its PreserVision® and OcuVite® brands, which directly compete with ZeaVision's EyePromise® eye health vitamins.

37. This cause of action arises out of ZeaVision's knowing and willful false and misleading labeling and/or promotion of its EyePromise® AREDS 2 Plus Multi-Vitamin, EyePromise® AREDS 2 Plus Zinc Free, and EyePromise® Zeaxanthin + Lutein products ("EyePromise® products").

38. Age-related macular degeneration ("AMD") is a leading cause of blindness in the developed world and accounts for more than 50% of all blindness in the United States. In 2001, the National Eye Institute (NEI) of the National Institutes of Health, completed a ten-year study, the Age-Related Eye Disease Study (AREDS), demonstrating that a daily oral supplementation comprising vitamin C, vitamin E, vitamin A in the form of beta-carotene, zinc, and copper reduced the risk of developing AMD by about 25% at 5 years.

39. In 2013, the second Age-Related Eye Disease Study (AREDS 2) was completed which tested whether adding lutein and zeaxanthin, the omega-3 fatty acids DHA and

EPA, or a combination of both to the AREDS formulation might further reduce the risk of progression to advanced AMD. A secondary goal of the AREDS 2 study was to test the effects of eliminating beta-carotene and reducing the zinc dose in the AREDS formulation. Based on the results of the AREDS 2 study, in 2013 the NEI recommended that the AREDS formula be adjusted by the removal of beta-carotene and the addition of lutein and zeaxanthin. The AREDS 2 researchers did not recommend that the amount of 80 mg of zinc proven effective in the AREDS study should be reduced based on the results of the AREDS 2 study. The results and conclusions were published as “Lutein + Zeaxanthin and Omega-3 Fatty Acids for Age-Related Macular Degeneration: The Age-Related Eye Disease Study 2 (AREDS 2) Randomized Clinical Trial,” Chew *et al.*, *J. Amer. Med. Assoc.* 309(19):2005-2015 (May 15, 2013).

Defendant’s False And/or Misleading Claims Concerning EyePromise® AREDS 2 Plus Multi-Vitamin

40. ZeaVision’s website www.eyepromise.com (“Website”) promotes and allows U.S. consumers to purchase its EyePromise® AREDS 2 Plus Multi-Vitamin product. A true and correct copy of the Website page promoting and offering the product for sale is attached hereto as Exhibit D.

41. On its Website, ZeaVision depicts the product packaging for the EyePromise® AREDS 2 Plus Multi-Vitamin product bearing the following claims:



42. ZeaVision's EyePromise® AREDS 2 Plus Multi-Vitamin packaging contains statements claiming that the product "supports . . . Enhanced vision" and contains ". . . a scientifically supported formula for better eyesight" with "***guaranteed*** improvement." (Emphasis added).

43. Additionally, ZeaVision's Website represents its EyePromise® AREDS 2 Plus Multi-Vitamin product is "***guaranteed*** to help support vision from age-related eye health issues" (emphasis added) and is formulated "[w]ith the safest daily recommended amount of zinc a healthy adult should consume . . ."

44. ZeaVision is knowingly and willfully mislabeling its EyePromise® AREDS 2 Plus Multi-Vitamin product in multiple ways, including claiming that: (1) the product offers "guaranteed improvement" and is "guaranteed to help . . ." when it cannot so guarantee; (2) the product is a "scientifically supported formula for better eyesight . . ." when it is not; and (3) the product contains "the safest daily recommended amount of zinc a healthy adult should consume with ingredients outlined in the National Eye Institute AREDS 2 study . . ." when it does not.

Defendant's False And/or Misleading Claims Concerning EyePromise® AREDS 2 Plus Zinc Free

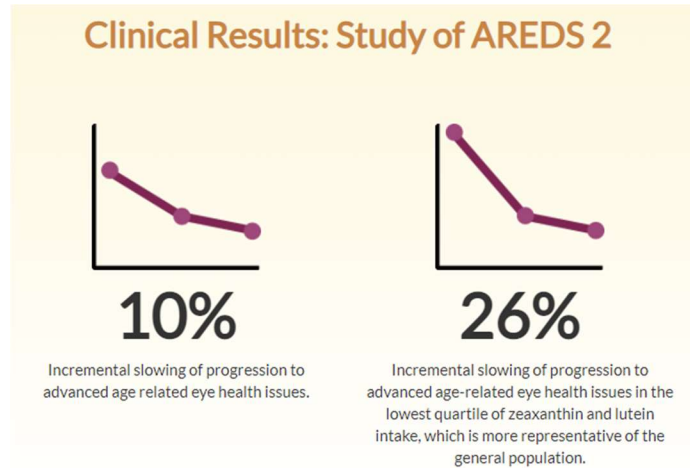
45. ZeaVision's Website promotes and allows U.S. consumers to purchase its EyePromise® AREDS 2 Plus Zinc Free product. A true and correct copy of the Website page promoting and offering the product for sale is attached hereto as Exhibit E.

46. The Website depicts the Supplement Facts Panel for the EyePromise® AREDS 2 Plus Zinc Free product below:

Supplement Facts		
Serving Size 2 Softgels Servings Per Container 30		
Amount Per Serving	% Daily Value*	
Calories	10	
Total Fat	0.5g	<1%
Vitamin C (as Ascorbic Acid)	500 mg	556%
Vitamin D (as Cholecalciferol)	50 mcg	250%
Vitamin E (as d-Alpha Tocopherol)	268 mg	1787%
Fish Oil 70%	250 mg	†
Total Omega-3 Fatty Acids A% (as EE)	190 mg	†
EPA (Eicosapentaenoic Acid) A%	100 mg	†
DHA (Docosahexaenoic Acid) A%	75 mg	†
Mixed Tocopherols	20 mg	†
Alpha Lipoic Acid	10 mg	†
Zeaxanthin	10 mg	†
Lutein	10 mg	†
*Percent Daily Values are based on a 2,000 calorie diet.		
† Daily Value not established.		

47. The Supplement Facts Panel for ZeaVision's EyePromise® AREDS 2 Plus Zinc Free product depicted on the Website represents that the product contains no zinc, which is not consistent with the recommendations from the AREDS or AREDS 2 studies.

48. Moreover, despite not containing zinc as recommended in the AREDS and AREDS 2 studies, ZeaVision indicates that its EyePromise® AREDS 2 Plus Zinc Free product conforms with the recommendations of the AREDS and AREDS 2 studies in multiple ways. One way is that ZeaVision represents that its EyePromise® AREDS 2 Plus Zinc Free product is “[b]acked by over 20 years of scientific research...,” and features two graphs depicting results of the AREDS 2 study, as shown below. See <https://www.eyepromise.com/product/areds-2-plus-zinc-free-2/>.



Another way is that ZeaVision’s Website represents that ZeaVision’s EyePromise® AREDS 2 Plus Zinc Free product contains “ingredients outlined in the National Eye Institute AREDS 2 study.” *See id.*

49. ZeaVision’s EyePromise® AREDS 2 Plus Zinc Free label contains a statement claiming that the product provides “**guaranteed** improvement.” (Emphasis added).

50. ZeaVision’s Website further represents that its EyePromise® AREDS 2 Plus Zinc Free product “[r]educe[s] blind spots and blurry areas in vision” and “[p]rotect[s] . . . from damaging blue light”. *See id.*

51. ZeaVision is knowingly and willfully mislabeling its EyePromise® AREDS 2 Plus Zinc Free product in multiple ways, including claiming that: (1) the product offers “guaranteed improvement” when it cannot so guarantee; (2) the product contains “ingredients outlined in the National Eye Institute AREDS 2 study . . .” when it does not; (3) the product contains “ingredients outlined in the National Eye Institute AREDS 2 study” when it does not; and (4) the product reduces “blind spots and blurry areas in vision” and protects eyes from “...damaging blue light” when it cannot so claim.

Defendant's False And/or Misleading Claims Concerning EyePromise® Zeaxanthin + Lutein

52. ZeaVision's Website promotes and allows U.S. consumers to purchase its EyePromise® Zeaxanthin + Lutein product. A true and correct copy of the Website page promoting and offering the product for sale is attached hereto as Exhibit F.

53. On its Website, ZeaVision includes the below description of its EyePromise® Zeaxanthin + Lutein product:

Zeaxanthin + Lutein is formulated to:

- Support and enhance vision naturally
- Help build up the defensive barrier responsible for protecting the back of the eye (where central and peripheral vision come from) from oxidants

54. ZeaVision is knowingly and willfully mislabeling its EyePromise® Zeaxanthin + Lutein product, including claiming that the product "enhance[s] vision naturally . . ." when it does not.

* * *

55. ZeaVision's labeling, promotion and marketing for its EyePromise® products, including but not limited to the above statements, are materially false and/or likely to mislead or confuse consumers since they misrepresent the nature and effectiveness of ZeaVision's products, which consumers purchase for eye health issues. These are material misrepresentations upon which consumers or potential consumers have relied and will rely upon.

56. ZeaVision's false and/or misleading statements are made in interstate commerce, including but not limited to, making the statements to the public through ZeaVision's Website.

57. ZeaVision has and continues to market and sell its EyePromise® products. ZeaVision's actions therefore mislead and harm consumers in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a).

58. ZeaVision's EyePromise® AREDS 2 Plus Multi-Vitamin and EyePromise® AREDS 2 Plus Zinc Free products compete with Bausch & Lomb's PreserVision® AREDS and AREDS 2 products. ZeaVision's EyePromise® Zeaxanthin + Lutein products compete with Bausch & Lomb's Ocuvite® eye health vitamins.

59. Through the false and/or materially misleading statements described, ZeaVision has caused its EyePromise® AREDS 2 Plus Multi-Vitamin and EyePromise® AREDS 2 Plus Zinc Free products to unfairly compete with Bausch & Lomb's PreserVision® AREDS and AREDS 2 products that are marketed as containing ingredients complying with the AREDS and AREDS 2 studies recommendations. ZeaVision has also caused its EyePromise® Zeaxanthin + Lutein products to unfairly compete with Bausch & Lomb's Ocuvite® products.

60. Upon information and belief, the distribution and sale of ZeaVision's EyePromise® products have caused and will continue to cause Bausch & Lomb to lose sales of its PreserVision® AREDS and AREDS 2 products and its Ocuvite® products, to both existing and future Bausch & Lomb customers.

61. Upon information and belief, ZeaVision's acts were undertaken willfully and deliberately and with the intention of causing confusion, mistake, or deception.

62. The aforesaid acts by ZeaVision have caused, and unless restrained and enjoined by this Court, will continue to cause irreparable harm, loss, and injury to Bausch & Lomb for which Bausch & Lomb has no adequate remedy at law.

PRAYER FOR RELIEF

63. WHEREFORE, Plaintiff Bausch & Lomb respectfully requests the following relief:

A. A judgment and decree that United States Patent No. 6,660,297 remains valid and enforceable;

B. A judgment that ZeaVision has infringed one or more claims of Bausch & Lomb's United States Patent No. 6,660,297;

C. A judgment that ZeaVision has induced infringement of one or more claims of Bausch & Lomb's United States Patent No. 6,660,297;

D. A judgment that ZeaVision has contributed to the infringement of one or more claims of Bausch & Lomb's United States Patent No. 6,660,297;

E. A judgment that ZeaVision has willfully infringed one or more claims of Bausch & Lomb's United States Patent No. 6,660,297;

F. A judgment and decree that United States Patent No. 8,603,522 remains valid and enforceable;

G. A judgment that ZeaVision has infringed one or more claims of Bausch & Lomb's United States Patent No. 8,603,522;

H. A judgment that ZeaVision has induced infringement of one or more claims of Bausch & Lomb's United States Patent No. 8,603,522;

I. A judgment that ZeaVision has contributed to the infringement of one or more claims of Bausch & Lomb's United States Patent No. 8,603,522;

J. A judgment that ZeaVision has willfully infringed one or more claims of Bausch & Lomb's United States Patent No. 8,603,522;

K. A permanent injunction restraining and enjoining ZeaVision, its officers, agents, attorneys and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of compositions and methods claimed in Bausch & Lomb's United States Patent Nos. 6,660,297 and 8,603,522 or components or materials especially made or especially adapted for use in an infringement of Bausch & Lomb's United States Patent Nos. 6,660,297 and 8,603,522;

L. An accounting of all damages to Bausch & Lomb arising from ZeaVision's infringement, inducement of infringement, contributory infringement and willful infringement, and that such damages be awarded to Bausch & Lomb together with interest;

M. A judgment and decree that ZeaVision, as a result of its willful, deliberate, and materially false statements regarding the quality and content of its products, has engaged in false advertising in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(b);

N. A permanent injunction ordering ZeaVision to, *inter alia*, immediately cease all distribution and sale of the EyePromise® products;

O. An order that ZeaVision recall all of the EyePromise® products currently in the marketplace;

P. An order that ZeaVision engage in a program of corrective advertising, satisfactory to Bausch & Lomb, to ameliorate the false and misleading information that ZeaVision has promulgated;

Q. An award of damages in an amount sufficient to compensate Bausch & Lomb for injury it has sustained as a consequence of ZeaVision's unlawful false advertising and unfair competition;

R. An award of enhanced damages in an amount sufficient to punish and deter ZeaVision from engaging in further knowing acts of false advertising;

S. A grant of the costs of this action and reasonable attorneys' fees incurred by Bausch & Lomb in connection with this action; and

T. Such other and further relief as the Court may deem just and proper.

February 8, 2021

Respectfully submitted,

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